PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

CITRO-SODA GRANULES

Each 4g of granules contains:

Sodium bicarbonate	1716 mg
Tartaric acid	858 mg
Citric acid	702 mg
Sodium citrate	613 mg

Contains sugar

Liquid glucose	356 mg

Contains Sweeteners

Saccharin sodium dihydrate	0,111 mg

Read all of this leaflet carefully because it contains important information for you.
CITRO-SODA Granules is available without a doctor's prescription for you to treat a mild illness. Nevertheless, you still need to use **CITRO-SODA** Granules carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- Do not share **CITRO-SODA** granules with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What **CITRO-SODA** is and what it is used for
2. What you need to know before you take **CITRO-SODA**
3. How to take **CITRO-SODA**
4. Possible side effects
5. How to store **CITRO-SODA**
6. Contents of the pack and other information

1. What CITRO-SODA granules is and what it is used for

- **CITRO-SODA** is a gastric antacid (neutralises excess acid in the stomach) and urinary alkalinising agent.
- **CITRO-SODA** can be used to alleviate symptoms of inflammatory conditions of the bladder.
- It can also be used to prevent crystalluria (formation of crystals in urine) during sulphonamide (antibiotic) treatment.

2. What you need to know before you take CITRO-SODA granules

Do not take CITRO-SODA granules:

- if you are hypersensitive (allergic) to Sodium bicarbonate, Tartaric acid, Citric acid, Sodium citrate or any of the other ingredients of **CITRO-SODA** granules;
- If you suffer from severe renal disease, metabolic disturbances with alkalosis, hypocalcaemia (low calcium in the blood) or hypochlorhydria (low level of stomach acid);
- If you are taking a urinary antiseptic which requires an acid urine, such as methenamine mandelate and methenamine Hippurate (see '**Other medicines and CITRO-SODA granules').**
- If you are on a special diet (if you have to limit the amount of sodium that you eat).

Warnings and precautions

CITRO-SODA granules contains liquid glucose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Taking frequent and large quantities of **Citro-Soda granules** may cause erosion of the teeth and have a local irritant action.

CITRO-SODA should be taken with care if you have any of the following:

- Kidney problems (renal insufficiency);
- heart failure (congestive cardiac failure);
- high blood pressure (hypertension);
- stomach ulcers (peptic ulcers);
- liver damage (liver cirrhosis);
- fluid accumulation (oedema) in the lungs or limbs;
- Pre-eclampsia (a type of pregnancy complication);
- Aldosteronism (a condition in which there is excessive secretion of a hormone aldosterone, which disturbs the balance of sodium, potassium, and water in the blood and so leads to high blood pressure.)

CITRO-SODA granules should not be given to patients with

- Respiratory alkalosis (rapidly increased breathing that changes the pH in the blood)
- Hypocalcaemia (low level of calcium in the blood)
- Hypochlorhydria (absent or low production of hydrochloric acid in the stomach).

Children and adolescents

CITRO-SODA is for use in children between the ages of 6 to 12 years old. **(see Section 3 "How to take Citro-Soda Granules"**)

Other medicines and CITRO-SODA granules

Always tell your health care professional if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please consult your doctor, pharmacist or other health care professional if you want to use **CITRO-SODA** but are taking the following medicines:

- Antacids (medicines that neutralise stomach acid)
- Quinolones (a type of antibiotic)
- Salicylates (medicines class use for relief of pain, fever and inflammation)
- Barbiturates (acts as a central nervous system depressant)
- Lithium (a type of medicine known as a mood stabiliser).

Do not take **CITRO-SODA** if you are using a medicine containing methenamine (a medicine used to treat infection of the urinary tract).

If you are taking any of the following medicines, **CITRO-SODA** must be taken at least 2 hours after these medicines:

- Tetracyclines (a type of antibiotic)
- Ketoconazole (an anti-fungal agent)

CITRO-SODA granules with food and drinks

Should not be taken by patients on a sodium-restricted diet.

Pregnancy and Breastfeeding

The safety of this formulation during pregnancy and breastfeeding has not been established.

Caution should be exercised when administered during breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery

None known.

CITRO-SODA contains liquid glucose and saccharin sodium dihydrate

CITRO-SODA granules contain liquid glucose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **CITRO-SODA**.

3. How to take CITRO-SODA granules

Always take **CITRO-SODA** exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dosage.

Adults:

One to two 5 ml medicine measures (4 g to 8 g) in half a glass of cold water 3 to 4 times daily, taken on an empty stomach and followed with additional water.

Drink the contents of the whole glass after effervescence.

Long-term therapy: One 5 ml (4 g) medicine measure daily.

Children (6 to 12 years of age):

One 5 ml medicine measure (4 g) in half a glass of cold water 2 to 3 times daily, taken on an empty stomach and followed with additional water.

Drink the contents of the whole glass after effervescence.

If you take more CITRO-SODA granules then you should:
The following signs and symptoms may indicate that you have overdosed on this product:
Metabolic alkalosis (rise in alkali level in blood)
Alkalosis (blood alkalinity) that may precipitate seizures
Hypernatraemia (too much sodium in the blood),
Hypokalaemia (electrolyte abnormality) causing symptoms that include mood changes, tiredness, slow breathing, muscle weakness, and irregular heart-beat.

If large concentrations of tartaric acid (as contained in CITRO-SODA) is ingested undiluted, it may cause violent vomiting and diarrhoea, abdominal pain, and thirst. Cardiovascular collapse or acute renal failure may follow. See under **'POSSIBLE SIDE EFFECTS'.**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take CITRO-SODA
Do not take a double dose to make up for forgotten individual doses.

4. **Possible side effects**

CITRO-SODA granules can have side effects.
Not all side effects reported for **CITRO-SODA** are included in this leaflet. Should your general health worsen or if you experience any undesirable effects while taking **CITRO-SODA**, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Stomach cramps,
- laxative effect (diarrhoea or loose bowel movements),
- Increased thirst
- Hypernatraemia (dizziness; fast heartbeat; high blood pressure; irritability; muscle twitching; increased thirst, restlessness; seizures; swelling of feet or lower legs; weakness) may occur.

Side effects with unknown frequency:

- Muscle hypertonicity, twitching and tetany may develop, especially in hypocalcaemic (the blood has too little calcium) patients.
- Metabolic alkalosis (rise in alkali level in blood): shortness of breath, muscle weakness and mental disturbances such as restlessness, convulsions and coma may occur especially in patients with renal dysfunction.
- Excessive doses may lead to sodium overloading (High sodium intake) and hyperosmolality (high sodium levels in the blood).
- Abdominal distension, flatulence (large amount of gas in stomach or intestine), belching (burping), and nausea may occur if the product is taken before effervescence is complete.
- Excessive doses may lead to hypokalaemia (electrolyte abnormality) causing symptoms that include mood changes, tiredness, slow breathing, muscle weakness, and irregular heart-beat.
- **Citro-Soda** granules are mildly irritant and if taken undiluted may cause violent vomiting and diarrhoea, abdominal pain, and thirst. Cardiovascular collapse or acute renal failure may follow**.**

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:
https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **CITRO-SODA** granules.

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

5. How to store CITRO-SODA

- Store all medicines out of reach and sight of children.
- Store in a cool (at or below 25°C), dry place.
- Keep in original packaging until required for use
- Do not use after the expiry date stated on the label and carton.

6. Contents of the pack and other information

What CITRO-SODA contains:

Each 4g of granules contains:

Sodium bicarbonate	1 716 mg
Tartaric acid	858 mg
Citric acid	702 mg
Sodium citrate	613 mg

Contains sugar

Liquid glucose	356 mg

Contains Sweeteners

Saccharin sodium dihydrate	0,111 mg

The other ingredients are:

Alcohol (ethanol) 190 proof, flavour lemon oil terpene-less.

What CITRO-SODA looks like and contents of the pack

Screw-top glass bottles contains 60 g, 100 g or 120 g and sachets contains 4 g packed into cartons of 2's, 8's, 30's and 44's.

CITRO-SODA granules consist of sweetened lemon flavoured granules. When added to water they effervesce and dissolve to form a clear alkaline solution which is lemon flavoured.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in:

14 June 2023

PATIENT INFORMATION LEAFLET

Registration number:

E1031 (Act 101/1965)

Botswana: BOT9700041 S4/ BOT0200525 S4

Namibia: NS0 04/18/1254

adcock ingram

31624 07/2023